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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,940	11/28/2000	Dale B. Schenk	15270J-004751US	9389

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EXAMINER

NICHOLS, CHRISTOPHER J 8

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,940

Applicant(s)

SCHENK, DALE B.

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 31-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 31-37, drawn to a *method* for preventing and/or treating an amyloid-related disease in a subject, comprising administering an **antigenic amount of a peptide** comprising at least one unnatural amino acid, classified in class 514, subclass 2, for example.
 - II. Claims 38-44, drawn to a *vaccine* for preventing and/or treating an amyloid-related disease in a subject, comprising an **antibody** raised against an antigenic amount of a peptide comprising at least one unnatural amino acid, classified in class 424, subclass 130.1, for example.
 - III. Claims 45-51, drawn to a *vaccine* for preventing and/or treating an amyloid-related disease in a subject, comprising an **antigenic amount of a peptide** comprising at least one unnatural amino acid, classified in class 530, subclass 300, for example.
 - IV. Claims 52-58, drawn to a *method* for preventing and/or treating an amyloid-related disease in a subject, comprising administering an **antibody** raised against an antigenic amount of a peptide comprising at least one unnatural amino acid, classified in class 424, subclass 130.1, for example.
2. The inventions are distinct, each from the other because of the following reasons:
3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is

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deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I and IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of administering an **antigenic amount of a peptide**, which is not required by any of the other Inventions. Invention IV requires search and consideration of an **antibody** raised against an antigenic amount of a peptide, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II and III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The **antigenic peptide** of Invention III can be used in materially different methods other than to make the antibody of Invention II, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the **antibody** of Invention II can be used to obtain the antigenic peptide of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

5. Inventions II and each of I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the antibody of Invention II can be used in *in situ* and diagnostic assays.

6. Inventions III and each of I and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antigenic peptide of Invention III can be used to isolate receptors.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. A β peptide
- b. An immunogenic fragment thereof
- c. A protein conjugate thereof
- d. An immunogenic derivative peptide thereof
- e. A peptidomimetic thereof

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 32, 39, 46, and 53 are generic.

If applicant selects any one of Inventions I, II, III, or IV, one species from the peptide group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher James Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
March 6, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600